IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

ALLIANCE FOR HIPPOCRATIC MEDICINE, *et al*.,

Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION, *et al*.,

Defendants.

Case No. 2:22-CV-00223-Z

UNOPPOSED MOTION OF FOOD AND DRUG LAW SCHOLARS FOR LEAVE TO FILE AN *AMICUS CURIAE* BRIEF IN SUPPORT OF DEFENDANTS

Under Fed. R. Civ. P. 7 and Local Rule 7.2(b), the *amici* food and drug law scholars respectfully move for leave to file a brief as *amici curiae* in the above-captioned case in support of Defendants' response in opposition to Plaintiffs' motion for a preliminary injunction. The proposed *amicus* brief is appended as an exhibit to this motion. Defendants and Plaintiffs have stipulated that they will not oppose the filing of amicus briefs. ECF No. 12.

IDENTITY AND INTERESTS OF *AMICI CURIAE*

The *amici* are 19 food and drug law scholars, all of whom are independent of the parties to this action, from 16 academic institutions across the United States.[1] Specifically, *amici* include:

- **Greer Donley, JD:** Greer Donley is the John E. Murray Faculty Scholar and Associate Professor of Law at the University of Pittsburgh Law School. Her research focuses on reproductive rights, FDA law, and health law.
- **Patricia J. Zettler, JD:** Patricia J. Zettler is an associate professor of law at The Ohio State University Moritz College of Law and a member of Ohio State's Drug Enforcement and Policy Center and its Comprehensive Cancer Center. Her research

[1] The views in the *amicus curiae* brief are those of the *amici* in their individual capacities and do not necessarily represent the views of their respective institutions.

focuses on FDA law and policy, and she is a co-author of the text *Food and Drug Law: Cases and Materials* (5th Edition 2022). Before her academic career, she served as an associate chief counsel in FDA's Office of the Chief Counsel.

- **R. Alta Charo, JD:** R. Alta Charo, Warren P. Knowles Professor Emerita of Law & Bioethics at the University of Wisconsin - Madison, is an expert in biotechnology regulation and policy. She previously served on President Clinton's National Bioethics Advisory Commission and was a senior policy advisor in the FDA Office of the Commissioner during the Obama administration, where she reviewed issues related to emerging technology regulation and drug safety.

- **I. Glenn Cohen, JD:** I. Glenn Cohen is a professor at Harvard Law School. His research focuses on bioethics and health law, with current projects in FDA law, abortion, and reproductive technologies.

- **Marsha N. Cohen, JD:** Marsha N. Cohen is an Honorable Raymond L. Sullivan Professor of Law at the UC Hastings College of the Law, San Francisco, where her expertise and scholarship focuses on federal food and drug safety law.

- **Nathan Cortez, JD:** Nathan Cortez, Callejo Endowed Professor of Law, Southern Methodist University, Dedman School of Law, is an expert in health, administrative, and FDA law, focusing on health care innovation and regulation. He is a co-author of the text *Food and Drug Law: Cases and Materials* (5th Edition 2022).

- **Rebecca S. Eisenberg, JD:** Rebecca S. Eisenberg, the Robert and Barbara Luciano Professor of Law at the University of Michigan Law School, focuses her scholarship on law and technology. She is an expert in biopharmaceutical research and has advised the National Institutes of Health. She has also taught courses in FDA law since 2000 and served as a member of the Committee on Law, Science & Technology of the National Academies of Sciences, Engineering & Medicine.

- **Henry T. Greely, JD:** Henry Greely is the Deane F. and Kate Edelman Johnson Professor of Law at Stanford Law School. He is an expert in genetics and focuses on biomedical technologies and ethical and social issues related to genetics and reproductive law. He teaches and writes on FDA law and issues arising from it.

- **George Horvath, MD, JD:** George Horvath is an Assistant Professor of Law at the University of Akron School of Law. His research and teaching focus on FDA Law and Health law.

- **Peter Barton Hutt, JD:** Peter Barton Hutt is a Senior Counsel at Covington & Burling LLP specializing in Food and Drug Law, and a former Chief Counsel of FDA. He is the lead co-author of the text *Food and Drug Law: Cases and Materials* (5th Edition 2022) and has taught a full course on the subject at Harvard Law School for thirty consecutive years.

- **Joan Krause, JD:** Joan Krause is the Dan K. Moore Distinguished Professor of Law at the University of North Carolina School of Law and focuses her research on health law, pharmaceutical law, criminal law, and women and the law. She has authored works on health care fraud and abuse, bioethics, and criminal issues affecting women.

- **Holly Fernandez Lynch, JD, MBE:** Holly Fernandez Lynch is an assistant professor of medical ethics and law at the University of Pennsylvania. Her research focuses on FDA pharmaceutical policy, access to investigational medicines, and clinical research ethics. She was previously the Executive Director of the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School.

- **Elizabeth McCuskey, JD:** Elizabeth McCuskey is a professor at Boston University School of Public Health and School of Law, and specializes in health reform. She has written on FDA preemption for SCOTUSBlog and was named a 2016 Health Law Scholar by the American Society for Law, Medicine, & Ethics.

- **Jennifer D. Oliva, JD, MBA:** Jennifer Oliva is a Professor of Law and Co-Director of the UCSF/UC Law Consortium on Law, Science and Health Policy at the University of California College of the Law, San Francisco. Her research focuses on health and privacy law, and she was awarded the 2021 Health Law Community Service Award by the AALS Section on Law, Medicine, and Health Care.

- **Jordan Paradise, JD:** Jordan Paradise is the Georgia Reithal Professor of Law and Co-Director of the Beazley Institute for Health Law & Policy at the Loyola University Chicago School of Law. Her research focuses on life sciences, legal and policy issues in pharmaceutical development, and medical devices.

- **Christopher Robertson, JD, PhD, MA:** Christopher Robertson, Professor of Law at Boston University Law School and Professor of Health Law, Policy & Management at the Boston University School of Public Health, focuses his scholarship on health law and bioethics.

- **Joanna Sax, JD, PhD:** Joanna Sax is the E. Donald Shapiro Professor of Law at California Western School of Law and her research focuses on the intersection of law and science, with special recognition for her work on FDA policies.

- **Allison M. Whelan, JD, MA:** Allison M. Whelan is an assistant professor of law at Georgia State University College of Law where her scholarship and teaching focuses on FDA law, reproductive justice, administrative law, and bioethics.

- **Diana Winters, JD, PhD, MA:** Diana Winters, the Director of the Health Law & Policy Program and the Deputy Director at the Resnick Center of Food Law & Policy at UCLA School of Law, is an expert in food and health law.

ARGUMENT

Courts have broad discretion when deciding whether to grant a motion for leave to file an *amicus* brief. *See Richardson v. Flores*, 979 F.3d 1102, 1106 (5th Cir. 2020); *see, e.g., Kinard v. Dish Network Co.*, 228 F. Supp. 3d 771, 777 (N.D. Tex. 2017). When deciding, courts generally consider whether information contained in the *amicus* brief "is timely and useful or otherwise necessary to the administration of justice." *United States ex rel. Long v. GSD & M Idea City LLC*, No. 11-cv-1154, 2014 WL 11321670, at *4 (N.D. Tex. Aug. 8, 2014) (quoting *Does 1-7 v. Round Rock Indep. Sch. Dist.*, 540 F. Supp. 2d 735, 739 n.2 (W.D. Tex. 2007)).

This motion and the attached brief are timely filed. *See* ECF Nos. 12 & 13. *Amici's* brief is also useful. *Amici* have collectively devoted decades to studying the Food and Drug Administration, with many holding particular expertise in the drug approval process. *Amici* seek to assist the Court with their expertise. In particular, *amici's* brief explains how Plaintiffs' motion mischaracterizes FDA's drug approval process, and how granting Plaintiffs' motion would destabilize the drug approval process far beyond the context of mifepristone's approval. *Amici's* brief provides information not present in the parties' briefs that will be useful to the Court as it considers the issues raised in this dispute.

Neither *amici* nor counsel received any monetary contributions to fund the preparation or submission of this brief and no party's counsel authored this brief in whole or in part.

For the foregoing reasons, the above-listed *amici* respectfully request this Court's leave to submit the attached *amicus curiae* brief for filing.

Dated: February 10, 2023

Respectfully submitted,

/s/ Richard Biggs
MULLIN HOARD & BROWN, LLP
Richard Biggs, SBN 24064899
Alysia Córdova, SBN 24074076
500 S. Taylor St., Suite 800
Amarillo, Texas 79101-1656
(806) 372-5050 telephone
(806) 372-5086 facsimile
rbiggs@mhba.com
acordova@mhba.com

COVINGTON & BURLING LLP
Lewis A. Grossman, D.C. Bar No. 442053*
Denise Esposito, D.C. Bar No. 445852*
Robert A. Long, D.C. Bar No. 415021*
Julia F. Post, D.C. Bar No. 1007771*
Beth Braiterman, D.C. Bar No. 1670850*
Emile Katz, D.C. Bar No. 90006190*
Guillaume Julian, D.C. Bar No. 90005136*
One CityCenter
850 Tenth Street, NW
Washington, DC 20001
(202) 662-6000 telephone
(202) 662-6291 facsimile
lgrossman@cov.com
desposito@cov.com
rlong@cov.com
jpost@cov.com
bbraiterman@cov.com
ekatz@cov.com
gjulian@cov.com

Robert J. Winson, Ca. Bar No. 326371
1999 Avenue of the Stars, Suite 3500
Los Angeles, CA 90067
(424) 332-4800 telephone
(424) 332-4749 facsimile
rwinson@cov.com

Counsel for Amici Food and Drug Law Scholars

**Pro hac vice* motion pending

CERTIFICATE OF CONFERENCE

In their Joint Motion to Extend Deadlines and Set Briefing Schedule, Plaintiffs and Defendants stipulated that they "w[ould] not oppose the filing of amicus briefs, and that any *amici* do not need to seek the specific consent of either Plaintiffs or Defendants before seeking leave of the Court." ECF No. 12 ¶ 3.

/s/ Robert J. Winson
Robert J. Winson

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing Unopposed Motion of Food and Drug Law Scholars for Leave to File an *Amicus Curiae* Brief in Support of Defendants was served on this 10th day of February, 2023 on all counsel of record via CM/ECF and filed consistent with Local Rule 5.1(e).

/s/ Robert J. Winson
Robert J. Winson